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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/855,287	05/15/2001	Arthur C. Coffey	7175-67882	1909

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EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 10/01/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/855,287

Applicant(s)

COFFEY, ARTHUR C.

Examiner

Lakshmi S Channavajjala

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,6-9,14-18,27,28, 30-37 and 39-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,6-9,14-18,27,28, 30-37 and 39-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2,3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Receipt of Information Disclosure Statement, dated 9-10-01; supplemental Information disclosure statement, dated 10-1-01 and response for restriction requirement, dated 6-19-02 is acknowledged.

Election/Restrictions

1. Applicant's election with traverse of group I in Paper No. 5 is acknowledged. The traversal is on the ground(s) that the line drawing between "collagen matrix" and "SIS" is hard to accept. This is not found persuasive because applicants have not explained how SIS and collagen matrix are similar, if not same. Further, the basis for restriction that collagen matrix is not necessarily derived from SIS, finds support from the instant specification, page 2, lines 1-8. Applicants define SIS as a tissue engineered collagen matrix obtained from small intestinal submucosa. Applicants also describe that SIS is one source of collagen, and there are several other sources of collagen matrices available, such as submucosa derived from stomach, bladder, respiratory or genitals; or collagen matrices from lamina propria and stratum compactum. Accordingly, the collagen matrix of group I is distinct from the SIS of group II.

The requirement is still deemed proper and is therefore made FINAL.

Status of Claims

2. Applicants canceled claims 3-5, 10-13, 19-26, 29 and 38 as non-elected group and presented new claims 39-43. Accordingly, claims 1, 2, 6-9, 14-18, 27, 28, 30-37 and 39-43 are pending prosecution.

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Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 12, 8, 9 and 4-18, rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Instant claim is indefinite because the claim recites "collagen matrix formed" but does not state how it is formed. It is examiner's understanding from a review of the instant disclosure that the invention utilizes a collagen layer from several sources but does not actual form collagen at the wound site. Accordingly, it is suggested that the word "formed" is replaced by "placed" so as to be consistent with the instant disclosure.

Claim 16 is indefinite because the claim describes that the semi-rigid wall of the structure has a lower member that is adjacent to patient's skin surrounding the wound. However, a review of the instant figures and the disclosure shows that the structure is not adjacent to the skin and instead is above the collagen layer, which in turn is adjacent to patient's skin.

Claims 16 and 33 recite "spaced-apart relationship", which is indefinite because it is unclear from the claims and from the instant disclosure as to what the term stands for. Instant disclosure does not provide any description of the positions of collagen and the structure, that reflects the claimed spaced-apart relationship, other than showing that collagen matrix is in direct contact with the wound, over which is placed the structure and covered by a wound cover. Accordingly, the term is without meets and bounds.

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4. Claim 16 recites the limitation "SIS layer" in lines 3 and 6. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 2, 8, 9, 14-18, 27, 28, 30-37 and 39-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,759,354 to Quarfoot in view of US 5,645,081 to Argenta et al (hereafter Argenta).

Instant claims are directed to a wound care bandage comprising a collagen matrix, a cover to seal the wound that is adapted for communication with a vacuum source, and a structure for placement between the collagen matrix and the wound cover.

Quarfoot teaches a wound dressing comprising a layer of collagen for placement directly over the wound, an absorbent adhesive layer for adhering the wound dressing to the skin and a thin outer vapor permeable layer, where in the absorbent adhesive layer extends beyond the periphery of the collagen layer such that it acts as a reservoir for the wound exudates (col. 2, lines 55-62 and col. 5-6). Thus, Quarfoot teaches elements a) and b) of instant claim 1. Quarfoot teaches that a wound dressing should ideally promote wound healing, provide protection against infection, minimize pooling of wound exudates, and yet allow subsequent aspiration (col. 2, lines 39-45). Quarfoot teaches that crosslinked collagen acts as a substrate favors cell growth and is

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very useful for wound and burn dressings (col. 3, lines 16-66). Quarfoot also teaches collagen can be obtained from sources such as intestine, dura mater, fascia, tail tendons etc., which are rich in connective tissues (col. 3, lines 9-15).

Quarfoot does not teach that the wound cover is adapted for communication with a vacuum source, as claimed in the instant. Quarfoot also differs from the instant claims in teaching a structure for placement between collagen matrix and cover, which is configured to provide a vacuum space.

Argenta teaches a method of treating tissue damage in burns and wounds (abstract, col. 1, lines 55-65). The apparatus of Argenta comprises a vacuum means for creating a negative pressure on the area of tissue surrounding the wound, sealing means operatively associated with the vacuum means to maintain negative pressure on the wound and a screen means to prevent overgrowth of tissue in the wound area. The screen means comprises a section of open-cell foam, which is porous, configured to be placed over a wound, into which is inserted a flexible tube for attachment to a suction pump. The sealing means comprises a polymeric sheet above the foam section and tubing such that it is adhered to the skin surrounding the wound (col. 2, lines 15-28). Argenta teaches that the screen means is a semi-rigid structure and is directly connected to the vacuum source (col. 4, lines 29-60). Argenta teaches application of pressure in cycles in alternate periods of application and non-application (col. 3, lines 9-18). Further, Argenta teaches that the method of applying negative pressure enables increased blood flow into the wound area, reduces the bacterial infection in the area and thus enhances wound healing and (col. 3, lines 29-46), which is also claimed in the instant method claims.

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Applicants admit that vacuum treatment bandages are known in the art, to draw exudates away from the wound and for increasing blood flow into the wound to provide accelerated wound healing. Applicants also discuss the teachings of Argenta in the instant specification (pages 2-3). Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to modify the wound dressing of Quarfoot by including a porous, semi-rigid screen structure and attaching it to a vacuum means through a hose or a tube, so as to apply a negative pressure to the wound which is being treated, because Argenta suggests that application of negative pressure to the wound restores the blood flow in to the wound resulting in reduced bacterial infection; and accelerates migration of epithelial and subcutaneous tissues from the border to the center of the wound so as to facilitate increased granulation, formation of extracellular matrix and neovascularization that aids in healing (col. 2, lines 44-68). With respect to the shape and placement of screen means of Argenta, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to place it on the collagen layer in the wound dressing of Quarfoot because collagen while adhering to the wound prevents loss of protein, fluid, electrolytes and hence should be in proximity to wound, followed by the screen means. Accordingly, placing the screen means between the collagen layer and the wound cover of Quarfoot with an expectation to prevent the loss of protein, fluid, electrolytes and at the same time allow blood flow into the wound for enhanced wound healing would have been within the scope of a skilled artisan. Further, Quarfoot does not teach first and second layers of collagen. However, absent showing criticality, adding collagen to the wound dressing as a single layer, several layers, without affecting the ability of collagen, in terms of drainage of wound exudates, enhanced cell growth, formation new granulation tissue, reduced infection and

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accelerate wound closure, would have been obvious to one of an ordinary skill in the art at the time of the instant invention.

6. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,759,354 to Quarfoot in view of US 5,645,081 to Argenta et al (hereafter Argenta) as applied to claims 1, 2, 8, 9, 14-18, 27, 28, 30-37 and 39-43 above, and further in view of US 6,440,427 to Wadstrom.

The wound dressings of Quarfoot and Argenta, discussed above, do not contain instant fibrin glue for holding collagen matrix.

Wadstrom teaches tissue treatment composition comprising fibrin or fibrinogen, and biodegradable polymers for wound healing or slow-release drug formulations etc (col. 1, lines 12-15). Wadstrom teaches fibrin is a known biological adhesive and is mixture of fibrin and thrombin that forms a coagulum (col. 1, lines 23-30). Wadstrom teaches fibrin sealants act in several ways, in hemostasis, glueing and wound healing. Further, Wadstrom teaches that fibrin sealants are used in a number of fields, especially for wound healing and prevention of adhesion of adjacent tissues (col. 3, lines 37-48).

It would have been obvious for one of an ordinary skill in the art at the time of the instant invention to use the fibrin sealant of Wadstrom in the wound dressing containing collagen (Quarfoot) and a vacuum means to apply negative pressure (Argenta) because Wadstrom suggests that fibrin glue, due it adhesive properties, is capable of atraumatically connecting tissues by forming a strong joint between them and adapts uneven wound surfaces, promotes in growth of fibroblasts, which in combination with efficient hemostasis and adhesion between the

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wound surfaces provides for an improved healing process. Further, Wadstrom teaches that fibrin glueing effect is increased by fibronectin binding to exposed collagen (col. 1, lines 57 through col. 2, lines 15). Accordingly, one of an ordinary skill in the art would expect that the wound dressing resulting from the teachings of Quarfoot and Argenta, further containing fibrin sealants of Wadstrom, exhibits enhanced binding of fibrin and collagen, and efficient wound healing due to increased hemostasis and in growth of fibroblasts, with reduced inflammation.

No claim allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 703-308-2438. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7924 for regular communications and 703-308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Lakshmi S Channavajjala
Examiner
Art Unit 1615
September 30, 2002